

Practitioner's Docket No. P-1109**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**In re application of: **JON M. MILLER**Application No.: **09 / 280,279**Group No.: **1617**Confirmation No.: **5533**Filed: **March 29, 1999**Examiner: **SHAHNAM J. SHARAREH**

For: **PREVENTION OR REVERSAL OF WEIGHT GAIN ASSOCIATED WITH THE USE OF  
ANTIPSYCHOTIC OR MOOD STABILIZING DRUGS BY MEANS OF THE USE OF HISTAMINE  
H<sub>2</sub>-RECEPTOR ANTAGONISTS**

Mail Stop **RCE**

Commissioner for Patents

P.O. Box 1450, Alexandria, VA 22313-1450

**REQUEST FOR CONTINUED EXAMINATION (RCE)  
(37 C.F.R. § 1.114)**

1. Applicant hereby requests continued examination, in accordance with 37 C.F.R. § 1.114, for the above identified application.

NOTE: 37 C.F.R. § 1.114 Request for continued examination:

"(a) If prosecution in an application is closed, an applicant may request continued examination of the application by filing a submission and the fee set forth in § 1.17(e) prior to the earliest of:

(1) Payment of the issue fee, unless a petition under § 1.313 is granted;

(2) Abandonment of the application; or

(3) The filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. 141, or the commencement of a civil action under 35 U.S.C. 145 or 146, unless the appeal or civil action is terminated.

(b) Prosecution in an application is closed as used in this section means that the application is under appeal, or that the last Office action is a final action (§ 1.113), a notice of allowance (§ 1.311), or an action that otherwise closes prosecution in the application.

**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

**37 C.F.R. § 1.8(a)**

- ☐ with sufficient postage as first class mail.

**37 C.F.R. § 1.10 \***

- ☒ as "Express Mail Post Office to Addressee"

Mailing Label No. EU760105634US (mandatory)**TRANSMISSION**

- ☐ facsimile transmitted to the Patent and Trademark Office, (703) \_\_\_\_\_

Signature

Holly Hart

(type or print name of person certifying)

Date August 2, 2004

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

(Request for Continued Examination (RCE) (37 C.F.R. § 1.114) [9-64]—page 1 of 6)

08/04/2004 AWONDAF1 00000045 09280279

01 FC:2801  
02 FC:2251385.00 OP  
55.00 OP

(c) A submission as used in this section includes, but is not limited to, an information disclosure statement, an amendment to the written description, claims, or drawings, new arguments, or new evidence in support of patentability. If reply to an Office action under 35 U.S.C. 132 is outstanding, the submission must meet the reply requirements of § 1.111.

(d) If an applicant timely files a submission and fee set forth in § 1.17(e), the Office will withdraw the finality of any Office action and the submission will be entered and considered. If an applicant files a request for continued examination under this section after appeal, but prior to a decision on the appeal, it will be treated as a request to withdraw the appeal and to reopen prosecution of the application before the examiner. An appeal brief under § 1.192 or a reply brief under § 1.193(b), or related papers, will not be considered a submission under this section."

**NOTE:** An applicant may file a submission under 37 CFR 1.114 containing only an information disclosure statement (37 CFR 1.97 and 1.98) in an application subject to a notice of allowance under 35 U.S.C. § 151. An appeal brief or a reply brief (or related papers) will not be considered a submission under 37 CFR 1.114. See 37 CFR 1.114(d). The submission, however, may consist of the arguments in a previously filed appeal brief or reply brief, or may simply consist of a statement that incorporates by reference the arguments in a previously filed appeal brief or reply brief. In addition, a previously filed amendment after final may satisfy this submission requirement. American Inventor's Protection Act of 1999, Question & Answer A5.

**NOTE:** Even though an RCE is improper (e.g., because it was filed before the prosecution is closed), an amendment submitted with the RCE will still be entered and considered by the examiner since it was timely filed and responsive to the non-final Office action in compliance with 37 CFR 1.111. American Inventor's Protection Act of 1999, Question & Answer A4.

**WARNING:** 35 U.S.C. 132(b) and § 1.114 provide for the continued examination of an application and not examination of a continuing application). Accordingly, the Office will not permit an applicant to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined. Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

**WARNING:** The provisions of 37 CFR 1.114 also do not apply (1) to a provisional application; (2) an application for a utility or plant patent filed under 35 U.S.C. 111(a) before June 8, 1995; (3) an international application filed under 35 U.S.C. 363 before June 8, 1995; (4) a patent under reexamination or (5) an application for a design patent. 37 CFR § 1.114(e).

**WARNING:** The PTO has pointed out why § 1.97(b) does not provide that an information disclosure statement will be considered if it is filed within three months after the date of a request for continued examination under § 1.114. The PTO explained that since an RCE filing is a reply under 35 U.S.C. 132, the applicant may be entitled to patent term adjustment if the Office does not act on an application containing a request for continued examination under § 1.114 within four months. See 35 U.S.C. 154(b)(1)(A)(ii). Thus, the Office cannot delay action on RCE applications for three months to determine whether an information disclosure statement will be filed. The Office, however, is adopting provisions (§ 1.103(c)) for a limited suspension of action after the filing of a request for continued examination under § 1.114, for the applicant to obtain additional time (prior to the issuance of the next Office action) to provide an information disclosure statement (or amendments, or an affidavit or declaration) after the filing of the RCE. See, Notice of August 16, 2000, "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule", 65 Fed. Reg., pages 50091-50105, at page 50100 (comment 11); OG: September 5, 2000, pages 13-24

**WARNING:** One of the time periods excluded from patent term adjustment is the time consumed by a continued examination request under 35 U.S.C. 132(b) (§ 1.114(b) (1)).

**WARNING:** The Office will not suspend action in an application when a reply by the applicant is outstanding. 35 U.S.C. 133 requires an applicant to "prosecute the application" within six months of an Office action (or a shorter period as set in the Office action) to avoid abandonment of the application. If an applicant files a request for continued examination but does not also provide any submission (in reply to the prior Office action) within the period for reply to the prior Office action, the application is abandoned by operation of law (35 U.S.C. 133).

The Office will treat a request for continued examination under § 1.114 containing a bona fide submission that is not fully responsive to the prior Office action under the practice set forth in § 1.135(c). In addition, under the limited suspension of action provisions of § 1.103(c), an applicant must still file a request for continued examination practice in compliance with § 1.114, but may obtain additional time (prior to the issuance of the next Office action) to provide an information disclosure statement, amendments, or an affidavit or declaration after the filing of the request for continued examination.

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See, Notice of August 16, 2000, "Request for Continued Examination Practice and Changes to Provisional Application Practice; Final Rule", 65 Fed. Reg., pages 50091-50105, at page 50102 (comment 20); OG: September 5, 2000, pages 13-24] Page 50102

**WARNING:** Section 1.97(b) does not provide that an information disclosure statement will be considered if it is filed within three months after the date of a request for continued examination under § 1.114.

**NOTE:** There is no limit to the number of times the fee for continued examination may be submitted. Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

**NOTE:** Unlike a continuation application, a continued examination request *can* utilize the mailing procedure of 37 CFR 1.8. See 37 CFR § 1.8(a)(2)(i)(A).

Continued Prosecution Request Fee \$ \_\_\_\_\_

### TIME REQUEST IS BEING MADE

2. This request is being submitted (check appropriate item(s) below):

- i. ☒ Prior to abandonment of the application
  - ii. ☐ Payment of the issue fee
    - ☐ Prior to payment of issue fee
    - ☐ Issue fee has been paid but a petition under § 1.313 has been granted
  - iii. ☐ Prior to a decision on appeal to the Board of Patent Appeals & Interferences
    - ☐ A notice is being separately sent to the Board of Patent Appeals & Interferences that this Request for Continued Examination is being filed.
- NOTE:** If such a notice is not sent to the Board then may refuse to vacate a decision rendered after the filing of the RCE but before recognition by the Office of the RCE request under § 1.114.
- iv. ☐ Appeal to the U.S. Court of Appeals of the Federal Circuit under 35 U.S.C. 145 or ☐ Commencement of a civil action under 35 U.S.C. 146
    - ☐ Prior to the filing of such appeal or commencement of civil action
    - ☐ Such appeal or commencement of civil action has been terminated

### ENCLOSURES

3. Enclosed herewith is/are:

**WARNING:** If reply to a final or non-final Office action under 35 U.S.C. 132 is outstanding, the submission must meet the reply requirements of § 1.111. 37 C.F.R. § 1.114(b).

- ☐ An information disclosure (37 C.F.R. § 1.98)
- ☐ Form PTO-1449 (PTO/SB/08A and 08B)
- ☒ An amendment
- ☒ New arguments
- ☐ New evidence in support of patentability
- ☐ Other:

Continued Prosecution Request Fee \$ \_\_\_\_\_

**FEE FOR REQUEST (37 C.F.R. § 1.17(e)).**

4. This application is on behalf of:

- ☒ Small entity (and status is still as small entity) . . . . . \$385.00  
☐ Other than a small entity . . . . . \$770.00

**FEE FOR CLAIMS**

NOTE: "The fee for continued examination under § 1.114 (§ 1.17(e)) does not include additional claims fee (cf. 1.53 (d)(3)(ii))." See Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.

37 CFR 1.53(d)(3): "The filing fee for a continued prosecution application filed under this paragraph is:

(i) The basic filing fee as set forth in § 1.16; and

Any additional § 1.16 fee due based on the number of claims remaining in the application after entry of any amendment accompanying the request for an application under this paragraph and entry of any amendments under § 1.116 unentered in the prior application which applicant has requested to be entered in the continued prosecution application."

5. The fee for claims (37 C.F.R. § 1.16(b)-(d)) has been calculated as shown below:

(Col. 1)	(Col. 2)	(Col. 3)	SMALL ENTITY	OTHER THAN A SMALL ENTITY
CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	ADDIT. RATE FEE OR	ADDIT. RATE FEE
TOTAL * 20	MINUS ** 28	=	x\$9= \$	x\$18= \$
INDEP. * 8	MINUS *** 8	=	x\$43= \$	x\$86= \$
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM			+ \$145= \$	+ \$290= \$
			TOTAL ADDIT. FEE \$	OR TOTAL ADDIT. FEE \$

\* If the entry in Col. 1 is less than entry in Col. 2, write "0" in Col. 3.

\*\* If the "Highest No. Previously Paid for" IN THIS SPACE is less than 20, enter "20."

\*\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3."

The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

**WARNING:** See 37 C.F.R. § 1.116.

(complete (a) or (b), as applicable)

(a) ☒ No additional fee is required.

OR

(b) ☐ Total additional fee required is \$ \_\_\_\_\_.

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## EXTENSION OF TIME

(If an extension of time is appropriate complete (a) or (b), as applicable)

6. The proceedings herein are for a patent application, and the provisions of 37 C.F.R. § 1.136(a) apply.

NOTE: 37 C.F.R. § 1.704(b) ". . . an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed. The period, or shortened statutory period, for reply that is set in the Office action or notice has no effect on the three-month period set forth in this paragraph."

- (a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked below:

Extension for (months)	Fee for other than small entity	Fee for small entity
<input checked="" type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 420.00	\$ 210.00
<input type="checkbox"/> three months	\$ 950.00	\$ 475.00
<input type="checkbox"/> four months	\$ 1,480.00	\$ 740.00

Fee: \$ 55.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured, and the fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ 55.00

OR

- (b) ☐ Applicant believes that no extension of time is required. However, this is a conditional petition and authorization to pay the necessary fees to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

## TOTAL FEE(S) DUE

**WARNING:** The fee for continued examination under § 1.114 may not be deferred. 37 C.F.R. § 1.53(f).

7. The total fee(s) due is/are:

Continued Prosecution Fee (§ 1.17(e))	\$ <u>385.00</u>
Fee(s) for additional claims (if any) (§ 1.16(b)-(d))	\$ _____
Extension of time fee (if any) (§ 1.17(a)(1)-(4))	\$ <u>55.00</u>
Total Fee(s) Due	\$ <u>440.00</u>

### PAYMENT OF FEE(S) DUE

8. Please pay the fee(s) for this continued examination application as follows:

- ☒ Check is attached for the sum of \$ 440.00  
☐ Charge Account \_\_\_\_\_ the sum of \$ \_\_\_\_\_  
☐ Charge Credit Card the sum of \$ \_\_\_\_\_  
(Credit Card Payment Form (PTO-2038) attached)

Please charge any required additional fee(s) for § 1.17(e), § 1.16(b)-(d) and/or § 1.17(a)(1)-(4) to

- ☒ Account 03-3420  
☐ Credit Card (Credit Card Payment Form (PTO-2038) attached).

### INVENTORSHIP

*NOTE: Any change of inventors must be via the procedure set forth in 37 CFR § 1.48. See Notice of March 10, 2000, 65 Fed Reg 14865, at 14868.*

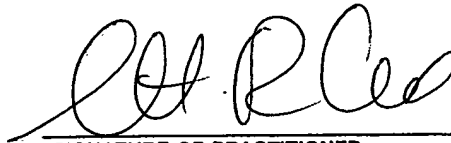
9. This application as amended names as inventors:

- ☒ the same inventors as previously designated for the claims.  
☐ fewer than the inventors previously designated and a statement accompanies this request for the deletion of the name or names of the person or persons who are not inventors of the invention now being claimed.  
☐ a person not named previously as an inventor and a petition under 37 C.F.R. § 1.48 is/has separately: ☐ being filed ☐ been filed

### DEFERRAL OF EXAMINATION

10. ☐ A request for deferral of examination accompanies this request for continued examination.

Reg. No.: 31,945



SIGNATURE OF PRACTITIONER

Tel. No.: ( 502 ) 589-4215

Scott R. Cox

(type or print name of practitioner)

400 West Market Street, Ste. 2200

P.O. Address

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Louisville, Kentucky 40202

(Request for Continued Examination (RCE) (37 C.F.R. § 1.114) [9-64]—page 6 of 6)



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	
Jon M. Miller	:	
	:	Art Unit: 1617
Serial No. 09/280,279	:	
	:	Examiner: Shahnam J.
Filing Date: March 29, 1999	:	Sharareh
	:	
Attorney Docket No. P-1109	:	Confirmation No.: 5533
	:	
For: PREVENTION OR REVERSAL OF	:	
WEIGHT GAIN ASSOCIATED WITH	:	
THE USE OF ANTIPSYCHOTIC OR	:	
MOOD STABILIZING DRUGS BY	:	
MEANS OF THE USE OF HISTAMINE	:	
H <sub>2</sub> -RECEPTOR ANTAGONISTS	:	

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## PRELIMINARY AMENDMENT

Background

The applicant filed a patent application on March 29, 1999. Pursuant to an Office Action of the United States Patent and Trademark Office dated April 6, 2004, the USPTO finally rejected Claims 29 - 32 and 34 under 35 USC §102(b) as being anticipated by Deutsch, et. al. The USPTO also rejected Claims 29 - 39 as being unpatentable over Rosenberg, U.S. Patent No. 5,897,910 in view of Deutsch, et. al.

The applicant files a Request for Continued Examination under 37 CFR § 1.114 with this Preliminary Amendment. This Preliminary Amendment contains a reply to the Office Action dated April 6, 2004.

Applicant respectfully asserts that this reply qualifies as a *bona fide* attempt to advance the application toward allowance and requests that all claims of the application contained in this Preliminary Amendment be reviewed and allowed.